

**Washington Health Care Authority (HCA): Hepatitis C Treatment Policy**  
**(February 25, 2015)**

The intent of this policy is to define clinical characteristics that all plans must use to identify patients who qualify for HCV treatment. It is the expectation that plans and providers will work together to remove barriers to ensure patients get the care they need according to this treatment policy in a timely manner. HCA Plans must cover hepatitis C treatment according to the following criteria.

**INCLUSION CRITERIA**

1. Baseline detectable HCV RNA viral load;

**AND**

2. HCV infection with cirrhosis<sup>1</sup> with a Metavir Score = F4 per liver biopsy or any **one** of the following:
  - a. Elastography
    - i. FibroScan  $\geq 12.5$  kPa<sup>2-3</sup>
    - ii. ARFI / PSWE  $\geq 2.34$  m/sec<sup>4-7</sup>
  - b. APRI  $> 2^3$
  - c. FibroTest  $\geq 0.75^8$
  - d. Other abdominal imaging where radiologist determines findings are suggestive of cirrhosis (e.g. nodules; enlarged liver, especially the left lobe; tortuous hepatic arteries; ascites; or portal hypertension);

**OR**

3. HCV Infection with severe fibrosis<sup>1</sup> with a Metavir score  $\geq$  F3 per liver biopsy or **two** of the following:
  - a. Elastography
    - i. FibroScan  $\geq 9.6$  kPa<sup>2-3</sup>; or
    - ii. ARFI / PSWE  $\geq 2.01$  m/sec<sup>4-7</sup>
  - b. APRI (AST to platelet ratio index)  $\geq 1.5^3$
  - c. FibroSURE  $\geq 0.49^3$

**OR**

4. HCV infection and HIV or HBV coinfection<sup>2</sup> with moderate fibrosis with a Metavir Fibrosis Score  $\geq$  F2 per liver biopsy or any **two** of the following:
  - a. Elastography
    - i. FibroScan  $\geq 7.1$  kPa<sup>2-3</sup>
    - ii. ARFI / PSWE  $\geq 1.38$  m/sec<sup>4-7</sup>
  - b. APRI  $\geq 1.0^3$
  - c. FibroSURE  $\geq 0.48^3$

**OR**

5. HCV infection and one of the following conditions:
  - a. Post solid organ transplant (e.g. Heart, Kidney, Liver)<sup>1,8-9</sup>
  - b. Awaiting Liver transplant<sup>1,8-9</sup>
  - c. Stage I-III Hepatocellular Carcinoma meeting Milan Criteria<sup>10</sup>
  - d. HCV Infection post liver transplant
  - e. Severe complications of HCV as defined below
    - i. Type 2 or Type 3 essential mixed cryoglobulinemia with end organ manifestations<sup>1</sup>
    - ii. HCV induced renal disease (e.g. Nephrotic syndrome or membranoproliferative glomerulonephritis (MPGN))<sup>1</sup>
  - f. Decompensated liver disease as defined by Child-Pugh-Turcotte classification score 7 – 12 (CPT Class B/C)<sup>13</sup> and MELD is  $\leq 20$ <sup>11</sup>;

**AND**

6. Patients satisfying one of the inclusion criteria in 1 through 5 with history of Alcohol Use Disorder must be abstinent from alcohol use for 6 months or longer<sup>1</sup>. Exceptions will be considered for patients who have abstained from alcohol for at least 3 months if they are:
  - a. Receiving treatment through a DBHR approved facility; or
  - b. under the care of an Addiction Medicine specialist; and
  - c. Abstain from alcohol use during treatment
  - d. ***Documentation supporting these exceptions will be required;***

**AND**

7. Patients satisfying one of the inclusion criteria in 1 through 5 with a history of IV drug use must be abstinent from IV drugs for at least 3 months<sup>12-15</sup>. Patients with IV drug use within the last 3 months will be considered for Hepatitis C treatment if they are receiving treatment, including medication assisted treatment when appropriate, through a DBHR approved facility, Addiction Medicine Specialist or a buprenorphine waived provider<sup>14-15</sup>. ***Documentation supporting these exceptions will be required.***

**EXCLUSION CRITERIA:** Patients with the following conditions are not eligible for HCV treatment

1. Pregnant or planning on becoming pregnant
2. Severe end organ disease and not eligible for transplant (e.g. heart, lung, kidney)
3. Clinically-significant illness or any other major medical disorder that may interfere with patients' ability to complete a course of treatment
4. Patients who in the professional judgment of the primary treating clinician would not achieve a long term clinical benefit from HCV treatment (e.g. patients: with multisystem organ failure; receiving palliative care; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)
5. MELD  $< 20$ <sup>16</sup> and one of the following:
  - a. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery

- b. Malignancy outside the liver not meeting oncologic criteria for cure
  - c. Hepatocellular carcinoma with metastatic spread
  - d. Intrahepatic cholangiocarcinoma
  - e. Hemangiosarcoma
  - f. Uncontrolled sepsis
6. Exclusion Criteria and Contraindications specific to SOFOSBUVIR<sup>17</sup> and LEDIPASVIR<sup>18</sup>
- a. Creatinine Clearance (CrCL) < 30 mL/min or on hemodialysis
  - b. Decompensated liver disease with CPT > 12 or MELD > 20<sup>11</sup>
  - c. Coadministration is not recommended
    - i. anticonvulsants (eg, carbamazepine, phenytoin, phenobarbital, and oxcarbazepine.
    - ii. antimycobacterials (eg, rifabutin, rifampin, and rifapentine.
    - iii. Elvitegravir/cobicistat/emtricitabine/tenofovir disproxil fumarate
    - iv. P-glycoprotein (P-gp) inducers (eg, rifampin, St. John's wort)
    - v. Rosuvastatin
    - vi. Simeprevir in combination with both sofosbuvir and Ledipasvir)
    - vii. Tipranavir/ritonavir
7. Exclusion criteria and contraindications specific to OMBITAVIR/PARITAPREVIR/t/ DASABUVIR<sup>19</sup>
- a. Decompensated liver disease with CPT ≥ 10
  - b. Coadministration with medications highly dependent on CYP3A for clearance and for which elevated concentrations may result in serious or life-threatening events (eg, alfuzosin, efavirenz, ergotamine, ergonovine, dihydroergotamine, methylergonovine, pimozide, sildenafil for PAH, simvastatin, lovastatin, triazolam, oral midazolam).
  - c. Coadministration with strong CYP3A and CYP2C8 inducers (eg, carbamazepine, phenobarbital, phenytoin, rifampin, St. John's wort)
  - d. Coadministration with strong CYP2C8 inhibitors (eg, gemfibrozil)
  - e. Coadministration with ethinyl estradiol-containing medications.
  - f. Coadministration is not recommended with voriconazole, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, and salmeterol.
8. Exclusion criteria and contraindications specific to interferon<sup>20</sup>.
- a. Platelet count <75,000
  - b. Severe mental health conditions that may be exacerbated by interferon;
  - c. Autoimmune hepatitis; Autoimmune diseases that may be exacerbated by interferon-mediated immune modulation;
  - d. Inability to complete a prior treatment course due to documented interferon-related adverse effects;
  - e. Hemoglobinopathies (thalassemia major and sickle cell) in combination with Ribavirin;
9. Child Pugh ≥ 6 (Class B and C) in cirrhotic patients; Exclusion criteria and contraindications specific to ribavirin<sup>21</sup>.
- a. Coadministration with didanosine
  - b. CrCl < 50 mL/min
  - c. Hemoglobinopathy

### **OTHER REQUIREMENTS FOR APPROVAL:**

1. Prescriber is a gastroenterologist, hepatologist or infectious disease specialist, or prescriber is participating in and consults with Project ECHO or one of the listed specialists (requires consultation note or documentation of phone call). Exceptions may be made for other non-specialist providers who work in coordination with an organized system of care, have received training in hepatitis C diagnosis, staging and treatment protocols, and have ready access to specialists that treat HCV<sup>1</sup>;

**AND**

2. Patient has attended a medical care visit with the treating clinician to discuss the pros and cons of antiviral therapy, the importance of adherence to treatment, and the risk factors for fibrosis progression.

**AND**

3. Patient must agree to participate in case-management or adherence monitoring program if required by the plan;

**AND**

4. Both the treating clinician and the patient must be confident that the patient can effectively start and successfully adhere to treatment. The treating clinician must attest that the patient has been evaluated for “psychosocial readiness” for treatment, including identification of potential impediments to effective treatment (e.g. difficulties with compliance, missing appointments, adequate social support, adequate control of mental health conditions). Potential impediments to successful treatment must be addressed prior to initiating treatment;

**AND**

5. Providers must agree to submit an HCV RNA viral load after completion of full course of antiviral treatment upon the request of the plan to track treatment success.

### **QUANTITY AND DISPENSING LIMITS**

Patients meeting the criteria above may receive HCV treatment. Approved antiviral regimens in Table 1 may be limited to 7 to 14 days supply per dispensing with exceptions for members with limited transportation to retail pharmacies. Plans may limit dispensing to a single specialty pharmacy with exceptions for members without stable mailing addresses.

**Appendix 1 HCA Approved Hepatitis C Treatment Regimens – See Attached  
(This table will be updated as new drugs and new evidence becomes available)**

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